IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

DEREK BAKER, on Behalf of himself and all Others Similarly Situated,	)	
Plaintiff,	)	
vs.	)	**Case No. 15-00222-CV-W-GAF**
NNW, LLC and HY-VEE, INC.,	)	
Defendants.	)	

ORDER

Presently before the Court are Defendants NNW, LLC's ("NNW") and Hy-Vee, Inc.'s ("Hy-Vee") (collectively "Defendants") Motions to Dismiss for failure to state a claim upon which relief can be granted, pursuant to Federal Rule of Civil Procedure 12(b)(6). (Docs. ## 13, 15). Plaintiff Derek Baker ("Plaintiff") opposes. (Doc. # 30). For the reasons set forth below, Defendants' Motions are GRANTED.

DISCUSSION

I. FACTS

Plaintiff's Petition alleges:

> This case is a class action brought on behalf of consumers who purchased a whey protein product called NNW Healthy 100% Whey ("Healthy 100% Whey") from 2009 through 2014. This lawsuit asserts that NNW and Hy-Vee deceptively marketed Healthy 100% Whey to their customers as containing high amounts of protein and minimal carbohydrates, when in fact Healthy 100% Whey contained small amounts of protein and was loaded with carbohydrates in the form of sugar and starch.

(Petition ¶ 1). Plaintiff alleges that Defendants claimed that all flavors of Healthy 100% Whey contained "pure whey protein concentrate" and "pure whey protein isolate" as their primary ingredients. (*Id.* ¶¶ 10, 55). In particular, Healthy 100% Whey purported to contain twenty-two

grams of protein, just one gram of carbohydrates, and just one gram of sugar per twenty-eight gram severing. (*Id.* ¶¶ 13, 50-52). However, Plaintiff claims that in fact, after subjecting Healthy 100% Whey to "quantitative nutrient lab analysis," the products tested contained less than five grams of protein, over twenty grams of carbohydrates, and over six grams of sugar per twenty-eight gram serving, as well consisting of over 50% starch. (*Id.* ¶¶ 17-18, 51-52).

Plaintiff, individually and on behalf of a class of similarly situated purchasers, alleged causes of action against Defendants arising under the Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407.010 *et seq.* (the "MMPA"), and for unjust enrichment. (*Id.* ¶ 22).

II. LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(b)(6), a court may dismiss a complaint that fails to state a claim upon which relief may be granted. When considering a Rule 12(b)(6) motion to dismiss, a court treats all well-pleaded facts as true and grants the non-moving party all reasonable inferences from the facts. *Westcott v. City of Omaha*, 901 F.2d 1486, 1488 (8th Cir. 1990). However, courts are "not bound to accept as true a legal conclusion couched as a factual allegation" and such "labels and conclusions" or "formulaic recitation[s] of the elements of a cause of action will not do." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)) (internal quotation marks omitted). A Rule 12(b)(6) motion should be granted only if the non-moving party fails to plead facts sufficient to state a claim "that is plausible on its face" and would entitle the party to the relief requested. *Twombly*, 550 U.S. at 570; *Wisdom v. First Midwest Bank, of Poplar Bluff*, 167 F.3d 402, 406 (8th Cir. 1999).

III. ANALYSIS

A. Preemption

Congress enacted the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*. (the "FDCA"), which in turn established the Food and Drug Administration (the "FDA"). 21 U.S.C. § 393(a). One of the responsibilities of the FDA is to ensure that foods are properly labeled. *Id.* § 393(b)(2)(A). In 1990, Congress passed the Nutrition Labeling and Education Act, 21 U.S.C. § 343 *et seq*. (the "NLEA"), establishing new requirements governing nutritional content labeling. *See Salazar v. Honest Tea, Inc.*, — F. Supp. 3d —, 2014 WL 2593601, at *3 (E.D. Cal. 2014).

Defendants argue that all of Plaintiff's claims are preempted by the FDCA and NLEA because Plaintiff does not allege that he tested the Healthy 100% Whey products under the methodologies mandated under these Acts. (*See* Doc. # 14, pp. 1-10; Doc. # 16, pp. 2-6).

The Supremacy Clause of the Constitution provides that "the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Thus, any state law that conflicts with an existing federal law is considered to be "without effect" and is preempted by the federal law. *See Maryland v. Louisiana*, 451 U.S. 725, 746 (1981) (citing *McCulloch v. Maryland*, 17 U.S. 316, 427 (1819)). The Eighth Circuit has distinguished between "complete" preemption and "ordinary" or express preemption. *Johnson v. MFA Petroleum Co.*, 701 F.3d 243, 248 (8th Cir. 2012). Complete preemption occurs "in limited circumstances where 'a federal law completely occupies the field of regulation so that by implication there is no room for state regulation and the coexistence of federal and state regulation is not possible.'" *Id.* (quoting *Mo. Bd. of Exam'rs for Hearing Instrument Specialists v. Hearing Help Express, Inc.*, 447 F.3d 1033, 1035 (8th Cir. 2006)). Express preemption applies "in situations where a state statute directly conflicts with federal law." *Id.* This occurs

when "Congress' intent [is] 'explicitly stated in the statute's language or implicitly contained in its structure and purpose.'" *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)). In preemption analysis, federal regulations carry the same preemptive effect as federal statutes. *Fid. Fed. Savings & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982).

The NLEA contains an express preemption section, which states that "no State . . . may directly or indirectly establish . . . any requirement for a food which is the subject of a standard of identity established under section 341 of this title that is not identical to" the FDCA requirements. 21 U.S.C. § 343-1(a). Thus, because of this express preemption provision, "states are not allowed to adopt food labeling requirement governed by the NLEA that are different from or additional to those required by the FDCA." *Salazar*, 2014 WL 2593601, at *4. However, at the same time, "the FDCA does not create a private right of action." *Id.* (quoting *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011) (internal quotation marks omitted). This does not mean that consumers are precluded entirely from bringing suits alleging food mislabeling. Rather, a state law is not preempted when the state law seeks to impose liability consistent with the FDCA. *See id.*; *see also Trazo v. Nestlé USA, Inc.*, Case No.: 5:12-CV-2272 PSG, 2013 WL 4083218, at *5 (N.D. Cal. Aug. 9, 2013) ("To avoid express preemption under Section 343-1(a), the plaintiff must be suing for conduct that *violates* the FDCA." (emphasis in original)).

There are many subsections of title twenty-one that establish conditions under which food is "deemed to be misbranded," such as section 343(a)(1), which states that food is "misbranded" when "its label is false or misleading in any particular." 21 U.S.C. § 343(a)(1). Further, there are two statutory sections of title twenty-one – sections 343(q) and (r) – that impose more

specific labeling requirements. Section 343(q) regulates "nutrient information" that food product labels must provide, such as the amount of sugar and total proteins contained in a serving. *Id.* § 343(q)(1)(D). Section 343(r) governs other statements about nutrient content; specifically, claims that "expressly or by implication," "characterize[] the level of any nutrient." *Id.* § 343(r)(I)(A).

FDA regulations provide that "[a] claim that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling . . . (that is, a nutrient content claim) may not be made on the label or in labeling of foods unless the claim is made in accordance with this [and other applicable] regulation[s]." 21 C.F.R. § 101.13(b). "An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., 'low sodium' or 'contains 100 calories.'" *Id.* § 101.13(b)(1). The regulation further provides that "compliance with requirements for nutrient content claims . . . will be determined using the analytical methodology prescribed for determining compliance with nutrition labeling in § 101.9." *Id.* § 101.13(o). This analytical methodology states:

> The sample for nutrient analysis shall consist of a composite of 12 subsamples (consumer units), taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot. Unless a particular method of analysis is specified in paragraph (c) of this section, composites shall be analyzed by appropriate methods as given in the "Official Methods of Analysis of the AOAC International," 15th Ed. (1990), which is incorporated by reference in accordance with 5 U.S.C. 552(a) or 1 CFR part 51 or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures.
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> 21 C.F.R. § 101.9(g)(2).

Defendants argue Plaintiff's claims are preempted because Plaintiff did not allege he subjected the Healthy 100% Whey to the methodology set forth in § 101.9(g). (Doc. # 14, pp. 1-10; Doc. # 16, pp. 2-6). Every court that has directly considered this issue has held that where "an FDA regulation provides that the question of compliance must be determined using the

method specified therein, a state law claim that seeks to establish a violation of such regulation by a different methodology is preempted." *Mee v. I A Nutrition, Inc.*, No. C-14-5006 MMC, 2015 WL 2251303, at *4 (N.D. Cal. May 13, 2015); *See Salazar*, 2014 WL 2593601, at *6 ("Accordingly, because defendant's label statements are nutrient content claims, their accuracy must be challenged under the 12-sample test method established by 21 C.F.R. § 101.9(g). Yet, the Complaint does not allege plaintiff tested [the product] using this method. Consequently, the Complaint does not show that defendant's statements on the product labels violate the FDCA's labeling requirements. Because plaintiff's allegations do not show a violation of the FDCA, plaintiff's state law claims are preempted; if allowed to proceed, the state law claims would impose liability inconsistent with the FDCA."); *Vital v. One World Co., LLC*, 2012 U.S. Dist. LEXIS 186203, at *2, 13-18 (C.D. Cal. Nov. 30, 2012) (granting summary judgment for the defendant regarding the plaintiffs' allegation that the defendant overstated the magnesium and sodium content of its coconut water because the "[p]laintiffs have not provided any evidence that the[ir] Report was conduct in accordance with the methodology mandated by the FDA under § 101.9(g)"); *see also Burke v. Weight Watchers Int'l, Inc.*, 983 F. Supp. 2d 478, 483 (D.N.J. 2013) (finding that the plaintiff's claims that the defendant misrepresented the caloric content of its ice cream bars were preempted because the plaintiff "has not pled that she tested the Ice Cream Candy Bar using every one of the Five Methods [set forth under 21 C.F.R. § 101.9]").[1]

[1] Plaintiff argues that *Salazar*, *Vital*, and *Burke* are wrongly decided and that this Court should follow the holding of *In re Simply Orange Orange Juice Marketing & Sales Practices Litigation*, MDL No. 2361, No. 4:12-MD-02361-FJG, 2013 WL 781785 (W.D. Mo. Mar. 1, 2013). (Doc. # 30, pp. 8-9, 13-14). However, the *Simply Orange* case is distinguishable from *Mee*, *Salazar*, *Vital*, *Burke*, and the case at bar. In *Simply Orange*, the plaintiffs challenged labelling on orange juice that purported the product was "100% pure squeezed," "not from concentrate," "Simply Orange," "pure," and "natural." *Simply Orange*, 2013 WL 781785, at *1. Each of these allegations regards the manufacturing process used to make the orange juice, which allowed the plaintiffs to determine that the labeling was false without separating the product into its chemical

Plaintiff's allegations are all premised on the argument that the nutritional labels on the packages of Healthy 100% Whey were deceptive.[2] Specifically, Plaintiff claims that Healthy 100% Whey purported to contain twenty-two grams of protein, just one gram of carbohydrates, and just one gram of sugar per twenty-eight gram severing, when in fact the products contain less than five grams of protein, over twenty grams of carbohydrates, and over six grams of sugar per twenty-eight gram serving, as well consisting of over 50% starch. (Petition ¶¶ 13, 17-18, 50-52). In his Petition, Plaintiff does not allege that he tested Healthy 100% under the twelve-subsample analytical methodology mandated by 21 C.F.R. § 101.9(g). (*See generally id.*). In fact, Plaintiff fails to articulate any precise methodology he used to determine that the Healthy 100% labels were deceptive. Rather, Plaintiff states in conclusory fashion that the labels are deceptive "[w]hen Healthy 100% Whey is subjected to quantitative nutrient analysis." (*Id.* ¶ 17). Accordingly, because Plaintiff does not allege that he subjected the Healthy 100% Whey to the Section 101.9(g) testing, his claims are preempted.[3]

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components. However, as discussed above, each of Plaintiff's claims is predicated upon the chemical composition of the Healthy 100% Whey being tested and analyzed.

[2] Plaintiff argues that a number of his claims are independent of the allegedly misleading labels, such as his "allegations regarding Healthy 100% Whey's adulterated nature and his allegations regarding the primary ingredients in Healthy 100% Whey." (Doc. # 30, pp. 11-12). However, these allegations are also premised on product test results. That is, Plaintiff cannot plausibly plead that the ingredients actually contained in Healthy 100% Whey are different than the ingredients stated on the labels without having subjected the product to chemical analysis. If this chemical analysis was not conducted under 21 C.F.R. § 101.9(g), Defendants could be subject to liability based on testing different from or additional to what is required by the FDCA. Under Plaintiff's argument, Defendants could be in compliance with the applicable FDA regulations under § 101.9(g), but nevertheless be liable under state law when Plaintiff utilizes a different testing methodology. This inequitable result forms the rationale for why state laws that impose standards different from or additional to those required by the FDCA are preempted.

[3] Defendants also argue that Plaintiff fails to meet the applicable pleading requirements. (Doc. # 14, pp. 11-12; Doc. # 16, pp. 7-10). Additionally, Hy-Vee argues that Plaintiff failed to plead fraud with the requisite particularity and that Hy-Vee is precluded from liability under

B. Leave to Amend

In Plaintiff's Opposition to Defendants' Motions to Dismiss, Plaintiff requested leave to amend his Petition under Federal Rule of Civil Procedure 15 if the Court finds that he has failed to allege a claim for relief. (Doc. # 30, p. 3 n.1). Under Rule 15, [t]he court should feely give leave [to amend] when justice so requires." Leave to amend should be freely granted unless "there exists undue delay, bad faith, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the non-moving party, or futility of the amendment." *Popoalii v. Corr. Med. Servs.*, 512 F.3d 488, 497 (8th Cir. 2008). However, "in order to preserve the right to amend the complaint, a party must submit the proposed amendment along with its motion." *Clayton v. White Hall Sch. Dist.*, 778 F.2d 457, 460 (8th Cir. 1985). Therefore, "[a]lthough ordinarily leave to amend should be freely granted, placing a footnote in a resistance to a motion to dismiss requesting leave to amend in the event of dismissal is insufficient." *Minneapolis Firefighters' Relief Ass'n v. MEMC Elec. Materials, Inc.*, 641 F.3d 1023, 1030 (8th Cir. 2011) (internal citation omitted); *see also Boyd v. Novastar Fin., Inc. (In re 2007 Novastar Fin. Inc., Sec. Litig.)*, 579 F.3d 878, 884 (8th Cir. 2009); *Dudek v. Prudential Sec., Inc.*, 295 F.3d 875, 880 (8th Cir. 2002); *Clayton*, 778 F.2d at 460. Accordingly, because Plaintiff has failed to submit a proposed amendment along with his request to amend his Petition, his leave for request to amend must be denied.

CONCLUSION

To allege a nutrient content claim, the product in question must be tested under the twelve-subsample analytical methodology set forth in 21 C.F.R. § 101.9(g). Here, Plaintiff fails to allege that he subjected Defendants' Healthy 100% Whey to this testing; rather, Plaintiff

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Missouri's Innocent Seller Statute, Mo. Rev. Stat. § 537.760. (Doc. # 16, pp. 10-15). As the Court finds that Plaintiff's claims are preempted, it need not address these additional arguments.

alleges in conclusory fashion that the products were subjected to "quantitative nutrient analysis." However, this is insufficient to avoid having his claims preempted by the FDCA and NLEA. Accordingly, for these reasons and the reasons set forth above, Defendants' Motion to dismiss Plaintiff's Petition are GRANTED. Further, Plaintiff failed to submit a proposed amendment with his request to amend his Petition. Accordingly, Plaintiff's request for leave to amend is DENIED.

IT IS SO ORDERED.

s/ Gary A. Fenner
Gary A. Fenner, Judge
United States District Court

DATED: July 8, 2015